UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 11, 1990

Mr. Luis A. Rivera Figueroa
Environmental Engineer
Abbott Laboratories
P.O. Box 278
Barceloneta, PR 00617

Dear Mr. Figueroa:

Thank you for your letter of June 27, 1990, in regard to your facility's compliance with the Part 259 medical waste regulations. As noted in the attached February, 1990, letter to Mr. Miguel Manzano, several of the quality control procedures at your facility do generate regulated medical wastes (RMW).

It is my understanding that Abbott Laboratories, located in Puerto Rico, has several production areas in which pharmaceuticals and diagnostic kits are manufactured and tested for quality. As you are aware, Section 259.30(a) defines regulated medical waste as any solid waste listed in Class 1-7 which is generated "in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings, or animals, in research pertaining thereto, or in the production or testing of biologicals……"

Section 259.10(b) defines biologicals as "preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing, or treating human beings or animals, or research pertaining thereto." Additionally, body fluids are defined as "liquids emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids, and semen and vaginal secretions."

Mr. Manzano has previously indicated that during the course of production, quality assurance/quality control (QA/QC) procedures are performed on diagnostic test kits and pharmaceuticals which contain "biologicals or body fluids." The wastes generated from the production or testing of products containing biologicals or body fluids are regulated medical wastes.

Environmental samples (i.e., swabs of table tops, floors, walls, etc., used to detect and control environmental contamination) which are taken within the general production areas would not be considered RMW. They are not considered RMW because they are not generated in the production or testing of biologicals and do not otherwise meet the definition of "medical waste." However, these

wastes may be indistinguishable from regulated medical waste. Therefore Abbott Laboratories may (choose to manage these wastes similarly to regulated medical waste.

If you have further questions or need additional information please contact Mary Greene at 202-475-7736.

Sincerely,

David Bussard, Director
Characterization and Assessment
Division

cc: George Meyers, Region II
Florida Forestier, EBQ, PR
Mary Jean Osborne, OWPE

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